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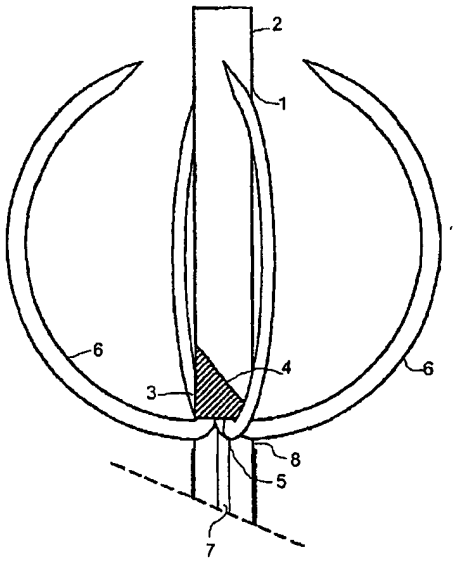
(54) Title: ELECTROSURGICAL PROBE FOR TUMOR TREATMENT BY RADIOFREQUENCY




(57) Abstract: The present invention relates to an electrosurgical probe comprising a metal cannula (1), partially provided with an electroinsulating coating, wherein a multiplicity of filiform electrodes in a stretched position is housed, which are provided with elastic memory for assuming an arched shape by coming out from the cannula (1) this way confining the action of the filiform electrodes to limited, nearly spherical volume. Said electrodes (6) are fixed to the distal end of a control rod (7) also arranged in a slidable way inside the cannula (1), so that the electrodes in a stretched position are arranged side by side parallely with their control rod (7). The cannula (1) is provided with a series of holes (8) each being positioned immediately under the free ends of the filiform electrodes (6) and having a sufficient diameter for the passage of said electrodes. These are taken out of the cannula (1) not by pushing, but by pulling the control rod (7).

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# "ELECTROSURGICAL PROBE FOR TUMOR TREATMENT BY RADIOFREQUENCY"

The present invention relates to an electrosurgical probe for the tumor treatment by radiofrequency energy, and particularly to a probe containing a multiplicity of needle-shaped electrodes whose tips can be expanded at the tumor to be treated so as to affect a volume of cancer tissue which is as large as possible.

The tumor treatment by hyperthermia which is induced by radiofrequency energy or other energy forms is already known in medicine. Electrosurgical probes provided with needle-shaped electrodes which, by penetrating into the cancer tissue, cause its necrosis, have already been developed. WO 96/29146 describes electrosurgical probes comprising a multiplicity of independent needle-shaped electrodes which are pushed inside the tissue to be treated by making them come out from the point of a metal cannula inserted into the patient's body. This is obtained by using electrodes formed of thin metal wires having an arched end provided with elastical memory which is kept in a substantially stretched condition inside said cannula and is released, expanding itself, when the electrodes are pushed out of the cannula in order to penetrate into the tissue to be treated. Object of said expansion is that a volume of cancer tissue to be treated which is as large as possible is affected. WO 98/52480 describes another electrosurgical probe which is also formed of a cannula containing a multiplicity of filiform electrodes having arched tips with elastic memory which are compressed inside the cannula in a stretched position and which expand themselves when they are pushed out of the cannula inserted inside the tissue to be treated. The filiform electrodes are arranged inside the cannula around a central nucleon so that, when their tips are pushed out from the point of the cannula, the cancer tissue is affected in a regular volume which is as assimilable as possible to a sphere.

However, none of the presently known electrosurgical probes is capable of creating an electrical field having a real spherical shape, by them it is at the most possible to obtain an electrical field having an ellipsoidal shape since, as it is

apparent from figures 4 and 5 of WO98/52480, only a small portion of the distal end of the metal cannula, which participates to the formation of the electrical field, is surrounded by the arched ends of the filiform electrodes.

Another drawback of the known electrosurgical probes is that their use involves the risk that the arched ends of the electrodes, by penetrating into the cancer tissue under the impulse of the suitable control, may go beyond the appointed target and penetrate also in vital structures, for instance a blood vessel, adjacent to the portion to be treated.

Therefore, object of the present invention is providing an electrosurgical probe of the type with multiple needles having an arched point with elastic memory which is free from the above mentioned drawbacks. Said object is achieved by the electrosurgical probe having the features specified in claim 1. Further features are specified in the following claims.

The electrosurgical probe according to the present invention eliminates the first of the above mentioned drawbacks of the probes according to the prior art, because it has the important feature that the electrodes, when they are outside the cannula, are arranged like the meridians of an ideal sphere whose diameter is formed of a long segment of the cannula distal portion, which is not coated by the insulating material. Accordingly, also the cannula in its distal portion participates in creating the active field of the radiofrequency. As a matter of facts, when the needle-shaped electrodes protrude from the cannula, the arched portion of each electrode forms an arc of 180° whose two ends are located near to the two ends of the uncoated distal portion of the cannula, that is, near to the two poles of the ideal sphere of which that portion of the cannula forms the diameter.

The second of the above mentioned drawbacks of the known electrosurgical probes is eliminated by means of the probe according to the present invention because it has the feature that the expansion of the arched tips of the electrodes is controlled by traction of the electrodes and not by thrust like in the known probes. In other words, whereas in the known probes the expansion of the filiform electrodes is controlled by a movement in the same direction of penetration of the electrodes into the patient's tissues, in the probe according to the present invention

the expansion is controlled by traction, that is by a movement in the opposite direction with respect to that of penetration of the electrodes into the patient's tissues. Resultingly, the free end of each filiform electrode will have the tendency to converge, after the expansion movement, towards the distal end of the metal cannula, thus avoiding the risk that it may diverge towards vital structures and perforate them. This is due to the fact that in the probe according to the present invention, in the rest position thereof, both the filiform electrodes and the rod which controls them have the same direction but they are turned in different directions after the expansion.

Besides eliminating the above mentioned drawbacks of the probes according to the prior art, the electrosurgical probe according to the present invention offers another important advantage, that is avoiding, during said operation, that the electrodes come out accidentally from the probe point during the positioning operation of the probe itself into the tissue. This is due to the fact that the operation for causing the electrodes expansion takes place by retraction with a movement in the opposite sense with respect to the positioning movement, and not in the same sense like in the prior art.

A further advantage of the electrosurgical probe according to the present invention with respect to the prior art is that no free space between the distal end of the cannula and the content thereof is provided. As a matter of fact, said free space, which is present in the known probes, may cause undesired phenomena of core boring of healthy tissue of the patient during the probe positioning operation. The structure of the probe according to the present invention allows also to close the distal end of the cannula and to confer it a pointed tip.

These and other advantages of the electrosurgical probe according to the present invention will be evident to those skilled in the art from the following detailed description of one embodiment thereof with reference to the accompanying drawings, wherein:

- figure 1 shows an enlarged and partially sectioned view in side elevation of the cannula of the probe according to the present invention;
- figure 2 shows a similar view of the same cannula of figure 1, but with

the arched tips of the electrodes taken out from the cannula and in the working position; and

- figure 3 shows a view in scale of a complete electrosurgical probe with the electrodes in the working position.

With reference to figure 1 there is shown that the electrosurgical probe according to the present invention comprises a metal cannula 1, of a known kind, inside which a head 3 is placed, having the upper end 4 preferably pointed like a flute mouthpiece. Also the point of cannula 1 can be pointed like a flute mouthpiece like the upper end 4 of head 3. In this way, the point of head 3 can coincide in the rest position with the point of cannula 1 without any free space between the two points. This structural measure avoids the undesirable phenomena of core boring of healthy parenchymatous tissue which occur by using the probes according to the prior art wherein a free space between the piston head which pushes the electrodes and the point of the cannula which contains them necessarily exists. It is obvious that the point of head 3 in the rest position can also protrude from the end 2 of the cannula, because this is open. However, constructive variants are possible, with a closed and sharp point of cannula 2, or with an open cannula 2 and a pointed head 3 like in figure 2. Other embodiments are obviously possible in order to fix the base of the electrodes to the distal end of their control rod so that in the stretched position they are side by side with said axis.

From base 5 of head 3 a multiplicity of filiform electrodes 6, as well as control rod 7 of head 3, branch off downwards. This is the most innovative and advantageous feature of the electrosurgical probe according to the present invention, with respect to that of the prior art wherein the electrodes in the stretched position form the prolongation of the electrode control rod and are not at the side thereof. The filiform electrodes having elastic memory of shape are already known in the art and therefore they do not need a detailed description.

The filiform electrodes 6 are arranged on the side and parallel to rod 7 in a stretched position with their downward turned tips which are near or slightly above a multiplicity of holes 8 arranged along the circumference of cannula 1.

The number of holes 8 corresponds to the number of electrodes 6 so that each electrode 6 has a relevant hole 8 for coming out of cannula 1 when rod 7 of head 3 is pulled downwards. Holes 8 are arranged in such a way that each of the electrode points can pass through the relevant hole 8 in order to get out of cannula 1 under the thrust of head 3 when this is pulled downwards. As soon as rod 7 is pulled downwards, electrodes 6 come out of holes 8 of cannula 1, gradually regaining their naturally arched shape by virtue of their elastic memory, thus assuming in the end the configuration shown in figure 2.

With reference to figure 2, there is shown that each electrode 6, after passing through the relevant hole 8, under the thrust of head 3 which is pulled downwards by means of control rod 7, has passed nearly completely through the relevant holes 8, thus penetrating in the cancer tissue to be treated or surrounding it. In the course of said penetration, by virtue of the elastic memory of which filiform electrodes 6 are provided, these expand themselves while bending until they assume the position shown in the figure. As it can be seen, each electrode 6 has assumed a position which greatly resembles that of a meridian of an ideal sphere. Said shape is much more regular than those which can be obtained by the electrosurgical probes according to the prior art. Said regularity depends substantially on the fact that filiform electrodes 6 are not only pushed inside the cancerous tissue, like in the known electrosurgical probes, but they are also guided from the lower ends of the relevant holes 8 suitably provided along the circumference of cannula 1.

Holes 8 can have any suitable shape for favoring the coming out of the needle-shaped electrodes and for guiding them upwards as soon as they come out from cannula 1. The preferred shape for holes 8 is the one slightly lengthened in the direction of the length of the needle-shaped electrode so as to favor the coming out thereof from cannula 1. The lower rim of the hole is provided with a profiled upward-turned cross-section which forms an upward-directed guide plane for the needle-shaped electrode which helps it in its expansion until it reaches the position shown in the figure.

Obviously, the number of the holes depends on the number of the filiform

electrodes. Their number varies according to the needs and can vary between two and twenty. In the embodiment shown in the figures 1-3 they are four. When the number of the filiform electrodes is very high, it is preferable that holes 8 are not circumferentially aligned on the surface of cannula 1, but arranged according to an elicoidal line or on more parallel circumferences.

Cannula 1 is provided with an insulating coating 9 of a plastic material whose upper edge is positioned slightly under the last of holes 8. In this way, the exposed portion of metal cannula 1 during working forms the diameter of the ideal sphere created by the envelope of the needle-shaped electrodes.

With reference to figure 3 there is shown an electrosurgical probe according to the present invention in the working position. In said position, the filiform electrodes 6 are already expanded and their points have reached a position very close to the distal end 2 of cannula 1. The coming out of electrodes 6 from the inside of cannula 2 has been caused by moving away head 3 from distal end 2 of the cannula. Said movement away has been achieved by pulling control rod 7 by means of knob 9 which is thus progressively removed from handle 10 which is internally provided with a room suitable for housing stem 11 of knob 9.

In figure 3 there is also shown the independent lateral needle 14 which works as a support for one or more thermistors of the telethermometric system applicable to the probe according to the present invention. Needle 14 comes out of cannula 1 through a suitable hole 15 made on the cannula and is controlled by cursor 12 which is partially housed inside knob 10. Further to lateral needle 14, the probe according to the present invention can be provided with one or more similar needles. Each one of needles 14 carrying thermistors can be rendered radiofrequency active at discretion, thus enlarging the extent of the thermolesion.

Obviously, the probe according to the present invention can be completed with the necessary connections to the radiofrequency generator and with all the other attachments necessary for its working, maintenance and use, as well as for the telethermometric check of the thermal lesion during the treatment.

In a preferred embodiment of the present invention, a thermistor has been applied on each end of the non insulated portion of cannula 1. A third thermistor

has been advantageously applied also on the insulated portion of cannula 1, immediately under holes 8.

Rigid cannula 1 can be replaced by a flexible tube in a portion comprised between the line of the holes 8 and handle 10. Said embodiment allows the probe to be used as a catheter.

CLAIMS

1. Electrosurgical probe comprising a metal cannula (1) provided with an electroinsulating coating wherein a multiplicity of filiform electrodes (6) is housed in a stretched position, which are provided with elastic memory for assuming an arched shape when they come out of the cannula (1) and fixed to the distal end of a control rod (7), this being also positioned in a slidable way inside the cannula (1), characterized in that the electrodes in a stretched position are arranged side by side parallely to their control rod (7) and that the cannula (1) is provided with a set of holes (8) each of which is positioned immediately under the free ends of the filiform electrodes (6) and have sufficient diameter for the passage of said electrodes.
2. Electrosurgical probe according to claim 1, characterized in that the distal end of the cannula (1) is provided with a segment which is not provided with an electroinsulating coating, said segment ending under holes (8).
3. Electrosurgical probe according to claim 1 or 2, characterized in that the electrodes (6) are fixed to the lower face (5) of a head (3) mounted on the distal end of the control rod (7).
4. Electrosurgical probe according to claim 3, characterized in that the rod (7) at the opposite end with respect to the one whereto the head (3) is fixed, is provided with a knob (9) for the seize thereof.
5. Electrosurgical probe according to claim 4, characterized in that the cannula (1) is provided with an internally hollow handle (10), for passing the rod (7) and for housing the stem (11) of knob (9).
6. Electrosurgical probe according to one or more preceding claims, characterized in that the holes (8) are in a number from one to twenty.
7. Electrosurgical probe according to one or more of the preceding claims, characterized in that it is provided with one or more needles (14) which bear, on the tip thereof, a thermistor for the control of the temperature.
8. Electrosurgical probe according to claim 7, characterized in that each of the needles (14) can be made radiofrequency active.
9. Electrosurgical probe according to one or more of the preceding claims,

characterized in that between the line of the holes (8) and the handle (10) the rigid cannula (1) is replaced by a segment of flexible tube.

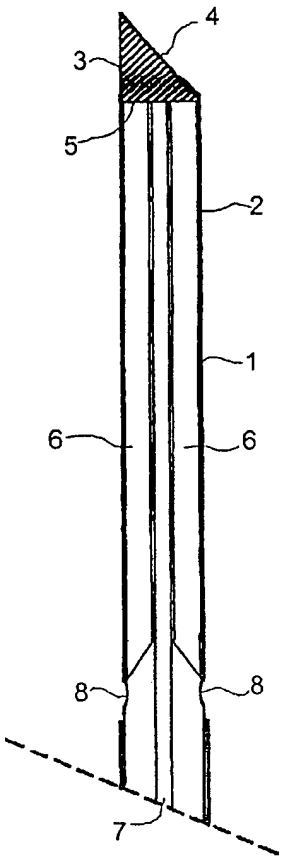


Fig. 1

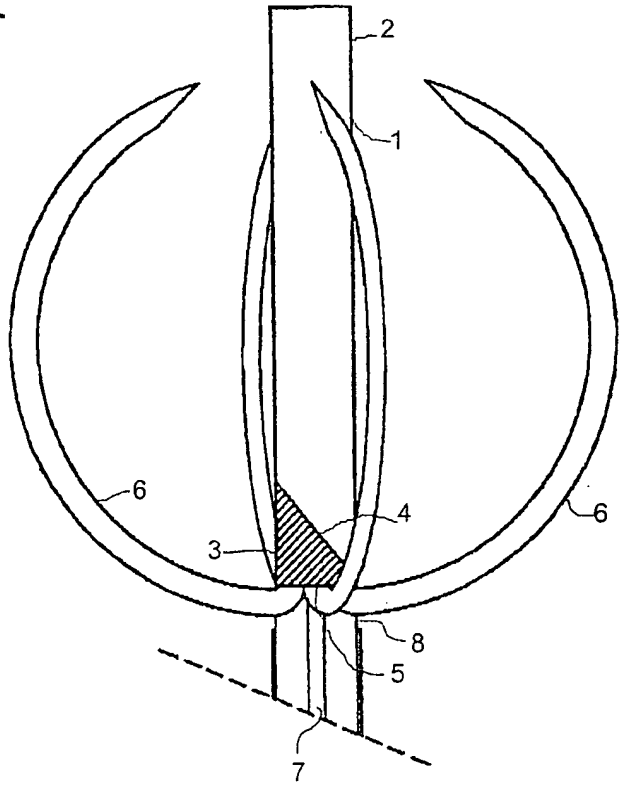


Fig. 2

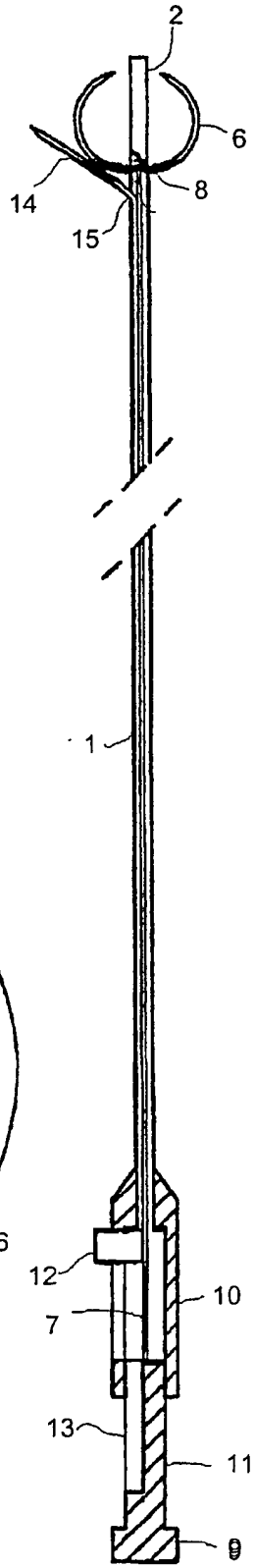


Fig. 3

# INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B18/14

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
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C. DOCUMENTS CONSIDERED TO BE RELEVANT

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☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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